

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SUN PHARMACEUTICAL INDUSTRIES LTD.
and
SUN PHARMACEUTICAL INDUSTRIES, INC.,

Petitioners

v.

NOVO NORDISK A/S,
Patent Owner

Case IPR2024-00107
Patent 10,335,462

PATENT OWNER'S FURTHER AUTHORIZED REPLY*

* Authorized by May 15, 2024 email from Trials. Emphases herein are added, and abbreviations/references are as in Paps.10 and 12.

LIST OF EXHIBITS

Exhibit	Description
EX2001	Excerpt of Defendants’ Initial Invalidity Contentions Regarding U.S. Patent Nos. 8,129,343; 8,536,122; 8,114,833; 8,920,383; 9,775,953; 9,457,154; and 10,335,462, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del. Oct. 20, 2022)
EX2002	Petition for <i>Inter Partes</i> Review, <i>Mylan Pharms. Inc. v. Novo Nordisk A/S</i> , IPR2023-00724, Pap.1 (Mar. 16, 2023)
EX2003	Declaration of Sayem Osman
EX2004	Stipulation and Order Regarding Trial of the MPI Ozempic Litigation, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC, Dkt. 245 (D. Del. Oct. 31, 2023)
EX2005	Nov. 29, 2023 Email from E. Goldschlager to Counsel, re: IPR2023-00724 – Request for Conference Call
EX2006	Scheduling Order, <i>Novo Nordisk Inc. v. Rio Biopharms., Inc.</i> , No. 1:22-cv-00294-CFC, Dkt. 22 (D. Del. June 30, 2022)
EX2007	Excerpt of Transcript of Dec. 13, 2023 Claim Construction Hearing, <i>Novo Nordisk Inc. v. Mylan Pharmaceuticals Inc.</i> , No. 23-101-CFC (D. Del. Dec. 13, 2023)
EX2008	Claim Construction Order, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC, Dkt. 148 (D. Del. July 25, 2023)
EX2009	Joint Stipulation and Order Amending Scheduling Order, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , MDL No. 22-MD-03038-CFC, Dkt. 268 (D. Del. Dec. 1, 2023)
EX2010	Excerpt of Novo Nordisk’s Third Amended Disclosures to Defendants Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries, Inc., <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del. July 28, 2023)
EX2011	U.S. Patent No. 8,114,833
EX2012	Summons in a Civil Action, Sun Pharmaceutical Industries, Inc., <i>Novo Nordisk Inc. v. Sun Pharmaceutical Indus. Ltd.</i> , No. 1:22-cv-00296-CFC, Dkt. 7 (D. Del. Mar. 7, 2022)
EX2013	Summons in a Civil Action, Sun Pharmaceutical Industries Ltd., <i>Novo Nordisk Inc. v. Sun Pharmaceutical Indus. Ltd.</i> , No. 1:22-cv-00296-CFC, Dkt. 8 (D. Del. Mar. 16, 2022)

Exhibit	Description
EX2014	Excerpt of Redacted Patent Owner's Response, <i>Mylan Pharms. Inc. v. Novo Nordisk A/S</i> , IPR2023-00724, Pap.30 (Jan. 17, 2023)
EX2015	Excerpt of Novo Nordisk's Initial Responses to Defendants' Initial Invalidity Contentions Regarding U.S. Patent Nos. 8,129,343; 8,536,122; 8,114,833; 8,920,383; 9,775,953; 9,457,154; and 10,335,462, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del. Dec. 21, 2022) [REDACTED]
EX2016	Transfer Order, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC, Dkt. 1 (D. Del. Aug. 5, 2022)
EX2017	INTENTIONALLY OMITTED
EX2018	Excerpt of Defendants' Second Supplemental Invalidity Contentions Regarding U.S. Patent Nos. 8,129,343; 8,536,122; 8,114,833; 8,920,383; 9,775,953; 9,457,154; and 10,335,462, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del. Jan. 12, 2024) [REDACTED]
EX2019	Novo Nordisk Production Letter, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del. Oct. 17, 2023) [REDACTED]
EX2020	Compilation of Defendants' Production Letters, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del.) [REDACTED]
EX2021	Compilation of Rule 30(b)(1) Deposition Notices, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del.)
EX2022	Notice of Service for Defendants' Initial Invalidity Contentions, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del. Oct. 20, 2022)
EX2023	Notice of Service for Defendants' Supplemental Invalidity Contentions, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del. Nov. 6, 2023)
EX2024	Stipulation for Extension of Time, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC, Dkt. 309 (D. Del. Feb. 9, 2024)
EX2025	February 26, 2024 Email from C. Ferenc to M. Raymond, re: IPR2024-00107

Exhibit	Description
EX2026	Sun Pharmaceutical Industries Ltd.’s and Sun Pharmaceutical Industries Inc.’s Stipulation of Invalidity Contentions, <i>Novo Nordisk Inc. v. Rio Biopharmaceuticals Inc.</i> , No. 22-cv-00294-CFC, Dkt. 275 (D. Del. Nov. 6, 2023)
EX2027	Joint Stipulation and Order Extending Deadline for Certain Fact Discovery, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC, Dkt. 305 (D. Del.)
EX2028	Excerpt of Opening Expert Report of Dr. John Bantle Regarding Invalidity of U.S. Patent No. 10,335,462, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del.)
EX2029	Excerpt of Opening Expert Report of William J. Jusko, Ph.D. Regarding Invalidity of U.S. Patent No. 10,335,462, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del.)
EX2030	Excerpt of Opening Expert Report of Dr. Paul Dalby Regarding Invalidity of U.S. Patent No. 10,335,462, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del.)
EX2031	Email Exchange Between Counsel for Petitioner and Counsel for Patent Owner Regarding Request To File Stipulation

Whether the Board considers Petitioner's ("Sun's") latest stipulation presents two significant questions of Board practice and policy: (1) whether a purported *Sotera* stipulation should be treated as dispositive when Sun admits it ***may still pursue the stipulated grounds "behind the scenes" in district court***, and (2) whether the Board, despite its discretion, will consider Sun's stipulation ***filed only 8 business days before institution is due***, especially when this is Sun's *third* attempt, and Sun unfairly used the developments and briefing in a related IPR to roadmap, delay and decide how little it could offer. Sun's latest, late stipulation should not be credited.

Regarding (1), PO asked Sun to confirm that, under its latest stipulation, Sun would not "contribute to district court litigation of any of the stipulated grounds behind the scenes (*e.g.*, Sun will not pay for experts, participate in expert reports, deposition preparation, etc. in connection with any of the stipulated grounds)." EX2031, 9-10 (May 3 email). ***Petitioner refused.*** EX2031, 9 (May 7 email). And Sun later complained it ***couldn't avoid this***, arguing the "issues for trial are [not] completely isolatable on all levels (which expert, how the expert spends and documents his time, how the expert expresses his opinions in reports and/or depositions)," and avoiding behind-the-scenes contributions would "impractical[ly] restrict[] Sun's ability to prepare its case on issues that it is not estopped from making." EX2031, 1 (May 13 email). Sun's groundwork is already laid: initially representing it retained different experts (Pap.2, 4, 6), Sun now shares those same experts in litigation to argue IPR

grounds with Mylan (violating Mylan’s own *Sand Revolution* stipulation (IPR2023-00724, Pap.1, 66)), Dr. Reddy’s, and parties who have not agreed to **any** estoppel. *See* EX2024, 10; EX2025, 9; EX2026, 6. *Cf.* Guidance, 7-8 (*Sotera* enables Board “to review grounds that... litigation **will not resolve**” and “avoid[] inconsistent outcomes”). As Petitioner won’t—and supposedly can’t—comply with its own “*Sotera*” stipulation, this meaningless stipulation should be ignored.

Regarding (2), Sun’s ever-changing, drip...drip...drip positions on estoppel—slowly roadmapping each of Dr. Reddy’s incremental IPR stipulations in IPR2024-00009—significantly prejudiced PO, and Sun’s Petition should be denied under §314(a). PO determined what substance to include in its POPR here based on Sun’s stated reliance on only *Sand Revolution*—allocating resources to *Fintiv* rather than, *e.g.*, additional substantive arguments based on Mylan’s experts’ deposition concessions, or seeking discovery of Petitioner’s relationship with Mylan and the remaining litigation defendants. Sun’s chosen timing here left time only for this short filing—not, *e.g.*, rebriefing the POPR (which, itself, would have been unjustifiably burdensome on PO). And Petitioner’s roadmapping of its submissions based on Dr. Reddy’s IPR constitutes harassing, burdensome, prejudicial gamesmanship meriting §314(a) denial (*see, e.g. Consolidated Trial Practice Guide*, 2 (aiming to “**streamlin[e] and converg[e]**... issues for decision [and] conduct proceedings in a **timely, fair, and efficient** manner”), 55-58). *Cf. General Plastic Indus. Co., Ltd. v.*

Canon Kabushiki Kaisha, IPR2016-01357, Pap. 19 (Sept. 6, 2017) (§II.B.4.i prece-
dential) (considering, *inter alia*, harassment, “potential for abuse,” “roadmap[ping],”
“fundamental fairness,” “efficiency,” and “prejudice” in analyzing discretionary de-
nial); *see Sonos, Inc. v. Google LLC*, IPR2023-01284, Pap. 10, 7-8 (Mar. 8, 2024).

The *Fintiv* guidance also does not require considering a *Sotera* stipulation re-
gardless of when it is filed. *BMW of North Am., LLC v. NorthStar Sys. LLC*,
IPR2023-01017, Pap.12 (Dec. 8, 2023) (observing need to file “well in advance”).
Considering Sun’s stipulation filed only 8 business days before the institution dead-
line would encourage gamesmanship, ever-changing positions until institution, and
more needless briefing. Institution should be denied based on *General Plastic*
(roadmapping) and *Fintiv*—including because of Petitioner’s chosen relationship
with other litigation defendants, and despite the December 2024 trial date (since
there is no one-year FWD deadline, given prior joinder). *Amerigen Pharms. Ltd. v.*
Janssen Oncology, Inc., IPR2016-00286, Pap.86 (Jan. 17, 2018) (FWD 19 months
after institution (Pap.14)); *West-Ward Pharms. Int’l Ltd. v. Novartis Pharms. Corp.*,
IPR2017-01592, Pap.78, 2-3 (Dec. 31, 2018) (FWD extended 6 months); Pap.12, 1.¹

Respectfully submitted: /Megan Raymond/

May 20, 2024

¹ To the extent claims challenged here are not asserted in the litigation, PO will not
seek to assert those claims against any Defendant there. *See* Pap.10 n.9.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of NOVO NORDISK’S FURTHER AUTHORIZED REPLY AND EXHIBITS 2031 have been served in their entirety on May 20, 2024, by causing the aforementioned documents to be electronically mailed to the following attorneys of record for the Petitioner listed below.

Petitioner’s Counsel of Record:

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Dated: May 20, 2024

Respectfully submitted,

By: /Sayem Osman/
Sayem Osman